for the Examiner's perusal. Accordingly, applicants respectfully request the Examiner to remove the instant objection since there are no Tables 1 and 2 on pages 9-10 of the instant specification for applicants to correct.

2. Rejection of Claim 1

The Official Action states that claim 1 is rejected for the following reasons:

> Claim 1 provides the use of a composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Applicants thank the Examiner for his suggestions regarding the claim. Applicants have replaced claim 1 with new claim 9 relating to a method of treatment rather than a use of a composition. Accordingly, applicants respectfully request the Examiner to reconsider and withdraw the rejection of pending claim 9.

3. Rejection of Claim 1 under 35 U.S.C. § 101

The Official Action states that claim 1 is rejected under 35 U.S.C. § 101.

As the basis of this rejection, the Official Action states:

> Claim 1 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678

> (Bd. App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). Because claim 1 is not directed to a statutorily recognized category of invention, claim 1 cannot be further examined on the merits.

Applicants respectfully traverse this rejection. Applicants thank the Examiner for her suggestions regarding the claims. Applicants have replaced claim 1 with new claim 9 relating to a method of treatment rather than a use of a composition.

Accordingly, applicants respectfully request the Examiner to reconsider and withdraw the rejection of pending claim 9.

4. Rejection of Claims 2-8 under 35 U.S.C. § 103(a)

The Official Action states that claims 2-8 are rejected under 35 U.S.C. § 103(a) as being obvious over the combined teachings of Morrow and Themy in view of Imai (BR 9201704), Fraser et al. (The Merck Veterinary Manual), VETU Abstracts 1985-63045, 1988-60359 and 1994-62049 and Kroschwitz et al. (Kirk-Othmer Encyclopedia of Chemical Technology).

As the basis of this rejection, the Official Action states:

> Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Morrow and Themy in view of Imai (BR 9201704), Fraser et al. (The Merck Veterinary Manual), VETU Abstracts 1985-63045, 1988-60359 and 1994-62049 and Kroschwitz et al. (Kirk-Othmer Encyclopedia of Chemical Technology).
> Morrow explicitly discloses the use of electrolyzed sodium chloride to treat the host animal for variety of pathogenic diseases (see from column 3, line 28 to column 5, line 19; Examples I, IV, X-XII, XVI, XVII; claims 1-6). Electrolysis reaction produces ozone and various oxychlorine species such as hypochlorous acid and hypochlorite (see from column 4, line 46 to column

5, line 19). Morrow also discloses the well-known fact that products resulting from electrolysis of saline solutions have long been known as in vitro microbicides, and have been used to keep water free of pathogenic organismes such as E. Coli (see from column 5, line 56 to column 6, line 9).

Themy explicitly discloses electrolyzed sodium chloride solutions (column 2, lines 9-47; Examples I, II, IX; claims 1-13). Electrolysis reaction produces ozone and various oxychlorine species such as hypochlorite (column 2, lines 24-40).

Imai (BR 9201704) discloses 10-100 ppm solutions of hypochlorite that have particle size range of 70-150 microns, which are sprayed to open areas, foodstuffs, as well as to people without damage to materials or eyes, for the control of cholera epidemics.

Fraser et al. (The Merck Veterinary Manual) discloses that intestinal diseases in pigs can be caused by variety of microorganisms (page 190). Chlorine compounds such as hypochlorite are known to be used as disinfectants, particularly for disinfecting water supplies (page 1530).

VETU Abstracts 1985-63045 discloses the use of sodium hypochlorite to disinfect swine pens to pens prevent diseases. VETU Abstract 1988-60359 teaches the importance of disinfectants in preventing coccidiosis in neonatal pigs. VETU Abstract 1994-62049 discloses the benefit of water disinfection as part of a therapy regimen to control infections of E. Coli, Newcastle disease and infectious bursal disease in broiler flocks.

Kroschwitz et al. (Kirk-Othmer Encyclopedia of Chemical Technology) are cited to establish that the electrochemical reactor features of the instant invention is conventional electrolysis technology that would have been within the skill of the ordinary skilled artisan (see pages 124-133, 135-140). Various oxychlorine species are disclosed upon electrolysis of a chloride solution (pages 133-135).

The cited references establish that electrolyzed aqueous solutions of sodium chloride is an old and known substance that has microbicidal activity for in vitro or in vivo uses. The references also establish that pathogenic microorganisms infect live animals and that use of disinfectants to disinfect and/or treat water supplies is a beneficial to controlling infections. Therefore, the ordinary skilled artisan

> would have been motivated to administer electrochemically "activated" solution of anion containing solutions such as aqueous sodium chloride solutions to live animals to control pathogenic infections. Motivation to atomize the electrolyzed solution arises from the known benefits of spraying atomized solutions of hypochlorite (a major component of electrolyzed solution) on human beings and various substrates, the ease of rapid administration to large number of live animals while also achieving disinfection of the treated area.
> For these reasons, the claimed invention, as a while, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been fairly suggested by the teachings of the cited references.

Applicants respectfully traverse this rejection. The references of record do not teach or suggest applicants' inventive subject matter as a whole as recited in the claims. The Examiner has failed to establish a *prima facie* case of obviousness against the presently rejected claims.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 U.S.P.Q.2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art reference must teach or suggest all the limitations of the

claims. *In re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970).

Morrow and Themy teach the use of electrolyzed sodium chloride to treat a host animal for pathogenic diseases, where electrolysis is used to produce ozone and various oxychlorine species such as hypochloruous acid and hypochlorite.

In contrast, presently pending claims 9-19 relate to a composition for use in the preparation of a medicament, and methods of using same, for treating pathogenic micro-organisms in live animals, wherein the composition comprises an anion-containing aqueous solution produced by an electro-chemical reaction. The anion-containing aqueous solution is so used because of its disinfectant abilities and seeks to minimize the adverse impact of an otherwise disruptive and traumatic treatment of an animal.

In general, an electrochemically activated, aqueous solution can be comprised of an anion-containing solution; a cation-containing solution; a mixture of an anion-containing and a cation-containing solution; an anion-containing solution having been prepared from an anion-containing solution, a cation-containing solution, or a mixture of an anion-containing solution and a cation-containing solution; and a cation-containing solution having been prepared from an anion-containing solution, a cation-containing solution, or a mixture of an anion-containing solution and a cation-containing solution. It is further generally accepted that such an electrochemically activated, aqueous solution may have a pH

ranging between 1 and 13. However, the presently claimed invention is directed solely to electrochemically activated, anion-containing aqueous solutions.

In contrast, neither Morrow nor Themy teach or suggest a composition comprising an electrochemically activated, aqueous solution specifically comprised of an anion-containing solution, for treating pathogenic microorganisms in live animals. Accordingly, presently pending claims 9-19 relate solely to a composition (and method) including an anion-containing solution of specific characteristics designed for treating pathogenic micro-organisms in live animals. The references cited by the Examiner do not disclose this critical element of the presently claimed invention. A person of ordinary skill in the art would have had no incentive to modify the teachings of Morrow and Themy to arrive at the presently claimed compositions as required by *In re Fine;* accordingly, the presently claimed invention is unobvious over the cited references.

Further, Themy teaches compositions and methods for the control of algae. However, algae are very different organisms from pathogenic micro-organisms. Accordingly, it would not have been obvious to a person of ordinary skill in the art to modify the teaching of Themy, directed to the control of algae, to arrive at the presently claimed invention, directed to the control of micro-organisms. Additionally, the same arguments as set forth above are applicable to Themy. Imai does not remedy these deficiencies.

Imai teaches spraying hypochlorite to open areas, foodstuffs, and the like to control cholera epidemics. In contrast, presently pending claims 9-19 relate to a composition comprising an electrochemically activated anion-containing aqueous solution of substantially independent pH and preferably in atomized form for treating pathogenic micro-organisms. It would not have been obvious to a person of ordinary skill in the art to extend a treatment for one disease, i.e. cholera, to the next disease, i.e. pathogenic micro-organisms in the respiratory and gastrointestinal tracts. Just as a person of ordinary skill in the art would not obviously use a medicine for treating a headache also to treat an upset stomach, such a person of ordinary skill in the art would have had no incentive to modify a reference teaching that hypochlorite can be used for treating cholera to arrive at the instant electrochemically activated anion-containing aqueous solutions of a salt which are successfully applied in treating pathogenic micro-organisms in the respiratory and gastrointestinal tracts of live animals.

In addition, applicants conducted experimental trials, inter alia in the United Kingdom, during which piglets were fogged for various periods of time. The initial thinking was that increased fogging periods would increase treatment results. However, after having subjected the piglets to fogging periods of 8 minutes for every period of 20 minutes, adverse side effects emerged, such as that the piglets started growing excessively long hair on their bodies and were continuously

sneezing. Through various trials the applicant optimized the fogging period as well as the droplet sizes. Accordingly, the mere fact that Imai suggests spraying hypochlorite in open areas and on foodstuffs does not translate into what the applicants are proposing in the presently claimed invention. Fraser and VETU do not remedy these deficiencies.

Fraser discloses the use of chlorine compounds as a disinfectant, for example in disinfecting water supplies, while the VETU abstracts disclose the use of sodium hypochlorite to disinfect swine pens. However, the use of an anion-containing solution according to the presently claimed invention overcomes the otherwise disruptive intervention of such a strong treatment in the respiratory and gastro-intestinal tracts of live animals. Kroschwitz does not remedy these deficiencies.

Applicants agree that the electrochemical reactor features of the invention is disclosed, inter alia, by Kroschwitz. However, applicants respectfully submit that Kroschwitz does not suggest the particular compositions, methods, and uses of the presently claimed invention. It is well known in the art that electrolytic cells are designed to achieve specific objectives. Different types of cells could produce different products from the same feedstock. It is also possible to operate the same electrolytic cell under different hydraulic, hydrodynamic, and electrical conditions and obtain products with specific and different characteristics, which have different compositions and concentrations and result in different microbicidal efficacy.

Additionally, applicants respectfully point out to the Examiner that veterinary treatments and medicines, such as those presently claimed, are very specific to the disease being treated. It is not obvious to, without a specific teaching in this direction, extend a treatment from one disease to the next. Further, it is well known that many materials used as a medicament in one application can often result in the manifestation of unwanted side effects in another application. For example, a person of ordinary skill in the art would appreciate that a medicine used to treat a headache would not obviously also treat an upset stomach.

So, too, it is common cause that not all micro-organisms are eliminated in the same manner. The very existence of a wide range of antibiotic and antimicrobial agents bears testimony to this fact. In order to eliminate different types of micro-organisms under different prevailing conditions, it is essential to use different types of preparations at different dosages, dosage rates and protocols, methods of application, contact periods, exposure times, and the like. It is submitted that the ordinary skilled person in the art would avoid blindly using the same recipe for elimination of different organisms. Neither Morrow nor Themy teach or suggest a composition comprising an electrochemically activated, aqueous solution comprised specifically of an anion-containing solution for treating pathogenic micro-organisms in live animals.

Further, none of the cited references teach or suggest that

the composition may be substantially pH independent. In fact, Morrow teaches that the composition has a substantially neutral pH. This would be a critical requirement for Morrow, since the composition is injected into the bloodstream of the patient, which is a pH sensitive vehicle.

In addition, one of the specific problems associated with pathogenic micro-organisms is that they are often present in the respiratory and gastrointestinal tracts of live animals. Atomizing a suitable dosage of the electrochemically activated anion-containing aqueous solution and dispensing the atomized dosage of aqueous anion-containing solution into an atmosphere, as suggested by pending claims 14-18, enables the effective and immediate treatment of the pathogenic micro-organisms by bringing the "medicine" in direct contact with the micro-organisms to be treated. Neither Morrow nor Themy suggest the atomizing of an electrochemically activated anion-containing aqueous solution for treatment purposes, but in fact teach injecting electrolyzed saline into the vascular system to effect intracellular passage of active agents into affected cells (see, e.g., Morrow, column 6, line 56).

When treating live animals with anionic solutions, it is of utmost importance to establish direct contact between the anion-containing solution and the pathogen. The problem that arises with pathogenic micro-organisms in live animals, especially respiratory and gastrointestinal pathogenic micro-organisms in animals such as piglets, for example, is that the animal

receives the organism while it is sucking on the mother. During this phase of its life, its small intestine are very acidic and the organisms are generally kept under control. However, after weaning, a proliferation of the pathogens is noted in the upper small intestine due to pH changes caused by the change from milk to a solid food diet.

It is known that gastro-intestinal pathogens may be eliminated from drinking water by the addition of products from electrolysis. However, the presently claimed invention suggests using the water merely as a vehicle for carrying the anionic solution to a site where pathogens are concentrated within the body of the animal. It is not concerned with the treatment of the water per se. In fact, the animal can consume the anion-containing solution without any water whatsoever. The advantages of adding the anion-containing solution to the drinking water of the animal is that it is passively administered to the animal - the more the animal dehydrates, the more water it consumes and the more anionic solution will reach the pathogen and destroy it.

In the case of respiratory pathogens, which may be present in the air space where the animal is kept, fogging or misting of the electrostatic anionic solution is employed to eliminate pathogens in the air space. Should the circulating pathogens enter the upper and/or lower sections of the respiratory system, the mist particles which are inhaled will be put in contact with the pathogen and kill it. In this instance, it is important to

note that the droplet sizes should be between 5 and 100 micrometers.

It would not have been obvious to a person of ordinary skill in the art to perform a method of treating pathogenic micro-organisms in a live animal through passive administration of an electro-chemically activated anion-containing aqueous solution to the animal in accordance with the presently claimed invention. There is no disruptive or dramatic intervention necessary, such as force-feeding or injection, to administer the solution according to the presently pending claims. The animal merely has to breathe or drink from its normal drinking water in order to take in the "medicine".

Additionally, presently pending claims 9-19 are based on the use of a flow-through electrolytic module (FEM), which has two cylindrical electrodes separated by a membrane in a co-axial arrangement, capable of producing two separate product streams, namely anolyte and catholyte. The hydraulic scheme may use recycling of at least part of one of the product streams through the same or the other chamber of the cell in order to achieve the desired level of activation and required properties in the product.

The anion-containing solution produced from this cell, with the characteristics specified in the patent, has sterilizing properties, with much higher levels of activation and microbicidal efficacy at lower levels of concentration than that produced by a plate reactor. The anion-containing solution is

of particular importance in the use of medical and veterinary applications where one does not wish to use chlorine (or other disinfectants such as gluteraldehyde), for example because of damage to instruments or because of skin or lung sensitivity. These include humidifiers, nasogastric tubes, endoscopes, nebulisers, etc. It is also important for the same reason in, for example, chicken coops, where the chickens can not be allowed to inhale chlorine.

The anion-containing solution produced in the FEM is capable of not only controlling, but also removing and eliminating pathogenic micro-organisms, and particularly respiratory and gastrointestinal pathogenic micro-organisms. Also, the anion-containing solution produced according to the invention has surfactant properties.

The references cited by the Examiner do not disclose each of the abovementioned critical elements of the presently claimed invention as required by *In re Wilson.* It is respectfully submitted that it would not have been obvious to a person of ordinary skill in the art to extrapolate the presently claimed invention from the teachings of Morrow and Themy, even when considered in view of the cited secondary references.

Accordingly, applicants respectfully requests the Examiner to reconsider and withdraw his rejections and allow all pending claims 9-19 presented herein.

5. Objection to the Declaration

The Official Action states that the declaration is

defective because:

> While the declaration states or indicates that the specification may have been amended, it is unclear when that amendment was made. "19" is unclear. Therefore, applicant's declaration fails to properly identify the specification for which applicant is making the declaration.

Applicants thank the Examiner for his suggestions regarding the declaration. Accordingly, applicants respectfully submit herewith a revised declaration from which the objected to term "19" has been removed, canceling the present grounds for objection.

CONCLUSION

Claims 9-19 are currently pending in the present application. Applicants respectfully request the Examiner to reconsider and withdraw the outstanding rejections of claims 1-8 and allow all pending claims 9-19 presented herein.

Respectfully submitted,
NATH & ASSOCIATES PLLC

Date: April 15, 2002

Gary M. Nath
Reg. No. 26,965
Joshua B. Goldberg
Reg. No. 44,126
Customer No. 20529

NATH & ASSOCIATES PLLC
1030 Fifteenth Street, N.W.
Sixth Floor
Washington, D.C. 20005-1503
Telephone: (202) 775-8383
Facsimile: (202) 775-8396
GMN:JBG:\roa.wpd

PATENT

Attorney Docket No. 23739

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

HINZE

Serial No: 09/529,734 Examiner: J. Pak

Filed: June 19, 2000 Art Unit: 1616

For: **USE OF AN AQUEOUS SOLUTION IN THE PREPARATION OF A MEDICAMENT FOR USE IN THE TREATMENT OF LIVE ANIMALS**

Appendix A

Please cancel claims 1-8 and insert the following new claims 9-19 as indicated in the following clean copy of the claims.

9. A method of treating pathogenic micro-organisms in a live animal, comprising administering a composition comprising an electrochemically activated, anion-containing aqueous solution to said live animal.

10. A composition for the preparation of a medicament for use in the treatment of pathogenic micro-organisms in a live animal, the composition comprising an electro-chemically activated anion-containing aqueous solution characterised wherein it is substantially pH independent, but has a redox

potential in excess of the redox potential of receiving water.

11. A composition according to claim 2 characterised wherein it has a redox potential of more than +400 mV.

12. A composition according to claim 2 characterised wherein the anion-containing aqueous solution is prepared by means of electrolysis of an aqueous solution of a salt.

13. A composition according to claim 2 characterised wherein the anion-containing aqueous solution is produced by an electro-chemical reactor, the electro-chemical reactor including a through-flow, electro-chemical cell having two co-axial cylindrical electrodes with a co-axial diaphragm between the electrodes so as to separate an annular inter-electrode space into a cathodic and an anodic chamber.

14. A method of treating respiratory and gastrointestinal pathogenic micro-organisms in a live animal, the method including the step of administering a dosage of a composition comprising an electrochemically activated, anion-containing aqueous solution to the animal.

15. The method according to claim 14 including at least

one of the steps of administering the solution by soaking, rinsing or dipping the animal in the solution; applying the solution as an inhalant via an atomising or fogging process; or administering the solution orally.

16. The method according to claim 15, wherein said orally administered solution is prepared by introducing the solution into drinking water of the animal.

17. The method according to claim 15 characterised wherein the atomising or fogging process includes the step of atomising the solution into the atmosphere for approximately 2 minutes in every period of 20 minutes.

18. The method according to claim 15 characterised wherein the atomising or fogging process includes the step of atomising the solution into the atmosphere in a volume to be treated, forming droplets of between 5 and 100 micrometer.

19. A composition according to claim 2 characterised wherein it has a redox potential of between +600 mV and +800 mV.

CLAIMS

1. The use of a composition in the preparation of a medicament for use in the treatment of pathogenic micro-organisms in a live animal, the composition comprising an electro-chemically activated, anion-containing aqueous solution.

2. A composition for the preparation of a medicament for the treatment of pathogenic micro-organisms in live animals, the composition comprising an electro-chemically activated anion-containing aqueous solution.

3. A method of treating pathogenic micro-organisms in a live animal, the method including the step of administering a dosage of a composition comprising an electro-chemically activated anion-containing aqueous solution to the animal

4. A composition as claimed in claim 2 wherein the anion-containing aqueous solution is prepared by means of electrolysis of an aqueous solution of a salt.

5. A composition as claimed in claim 2 wherein the anion-containing solution is produced by an electro-chemical reactor, the electro-chemical

reactor including a through flow, electro-chemical cell having two co-axial cylindrical electrodes with a co-axial diaphragm between the electrodes so as to separate an annular inter electrode space into a catalytic and an analytic chamber.

6. A composition as claimed in claim 2 wherein the anion containing aqueous solution has a redox potential up to about ÷600 mV and 800 mV and a pH of about 6,5 to 7,5.

7. A method of treatment as claimed in claim 3 including at least one of the steps of administering the solution by soaking, rinsing or dipping the animal in the solution, applying the solution as an inhalant via an atomising or fogging process, and administering the solution orally.

8. A method as claimed in claim 7 wherein the atomising or fogging process includes the step of atomising the solution into the atmosphere in a volume to be treated, forming droplets of between 5 and 100 micrometre..